DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 18, 2015

Halyard Health
Ms. Christine L Macauley
Technical Leader, Regulatory Affairs
5405 Windward Parkway
Alpharetta, GA 30004

Re: K150113
Trade/Device Name: Fusion Black Powder-Free Nitrile Exam Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Medical Exam Gloves
Regulatory Class: I
Product Code: LZA
Dated: May 19, 2015
Received: May 21, 2015

Dear Ms. Macauley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K150113

Device Name

Halyard® Fusion Black Powder-Free Nitrile Exam Glove

Indications for Use *(Describe)*

The Halyard ® Fusion Black Powder-Free Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 2 – 510(k) Summary

Date Summary was Prepared: June 16, 2015

510(k) Submitter:
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Primary Contact for this 510(k) Submission:
Same
Halyard Health
5405 Windward Parkway
Alpharetta, GA 30004

Device Trade Name: Halyard® Fusion Black Powder-Free Nitrile Exam Glove

Device Common Name: Medical Exam Gloves

Device Product Code and Classification Name:
LZA
Class I, 21 CFR §880.6250
Patient Examination Glove

Predicate Device:
K081260
Kimberly-Clark Lavender Nitrile Powder-Free Exam Gloves

Subject Device Description: Halyard® Fusion Black Powder-Free Nitrile Exam Gloves are disposable, black-colored, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination gloves which are chlorinated on the donning side and are packed in a cardboard dispenser box.

Intended Use: The Halyard® Fusion Powder-Free Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

	Subject Device	Predicate Device K081260	Substantially Equivalent
FDA Product Code	LZA	LZA	Yes
FDA Classification	Class 1	Class 1	Yes
Common Name	Medical Exam Glove	Medical Exam Glove	Yes
Device Trade Name	Halyard Fusion Black Nitrile Powder-Free Exam Glove	Kimberly-Clark Lavender Nitrile Powder-Free Exam Glove	Yes
Intended Use	The Halyard Fusion Black Powder-Free Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	The Kimberly-Clark Lavender Nitrile Powder-Free Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Yes

Halyard Health
510(k) for the Halyard® Fusion Black Powder-Free Nitrile Exam Glove – 510(k) Summary

	Subject Device	Predicate Device K081260	Substantially Equivalent
Technological Characteristics	Black colored, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination glove.	Lavender colored, nitrile, powder-free, textured fingertip, ambidextrous, non-sterile patient examination glove.	Yes
Performance Data			
ASTM D5151 Standard Test Method for Detection of Holes in Medical Gloves	Testing of the subject device shows it meets the 2.5 AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard.	Testing of the subject device shows it meets the 2.5 AQL requirement in the standards for leakage. The device meets the acceptance criteria of the standard.	Yes
ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Applications	The physical dimensions of the subject device are within the limits of the standard and the physical properties of the subject device meet the requirements for tensile strength and elongation in the standard. Therefore the device meets the acceptance criteria of the standard.	The physical dimensions of the subject device are within the limits of the standard and the physical properties of the subject device meet the requirements for tensile strength and elongation in the standard. Therefore the device meets the acceptance criteria of the standard.	Yes
ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves	Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free.	Residual powder on the subject device is within the powder-free limit of < 2 mg maximum powder per glove and meets the acceptance criteria for powder-free.	Yes
ISO 10993-10 Biological evaluation of medical devices -Tests for Irritation	**Acceptance criteria:** Erythema/ edema up to 72 hours post exposure. **Result:** Erythema/edema was negligible. Meets acceptance criteria.	**Acceptance criteria:** Erythema/edema up to 72 hours post exposure. **Result:** Erythema/edema was negligible. Meets acceptance criteria.	Yes
ISO 10993-10 Biological evaluation of medical devices -Tests for Skin Sensitization	**Acceptance criteria:** No evidence of delayed dermal contact sensitivity at 24 and 48 hours post injection. **Result:** Not a sensitizer under conditions of the study. Meets acceptance criteria.	**Acceptance criteria:** No evidence of delayed dermal contact sensitivity at 24 and 48 hours post injection. **Result:** Not a sensitizer under conditions of the study. Meets acceptance criteria.	Yes
ISO 10993 Biological evaluation of medical devices - Tests for Systemic Toxicity	**Acceptance criteria:** No signs of systemic toxicity up to 72 hours post injection. **Result:** No systemic toxicity observed. Meets acceptance criteria.	**Acceptance criteria**: No signs of systemic toxicity up to 72 hours post injection. **Result:** No systemic toxicity observed. Meets acceptance criteria.	Yes
Conclusion	The performance data support the conclusion that the subject device is as safe, as effective, and performs as well as the legally marketed device that was submitted and cleared under K081260.		

Technological Characteristics and Substantial Equivalence:

The Halyard® Fusion Black Powder-Free Nitrile Exam Glove is substantially equivalent to the predicate device, Kimberly-Clark Lavender Nitrile Powder-Free Exam Gloves (K081260). The only difference is the addition of fourteen pigments that have been tested for biocompatibility. This addition of pigments raises no new issues of safety and efficacy as demonstrated by testing of biocompatibility and technical product performance as described in this 510(k) submission.

Summary of Testing: These gloves have been tested for conformance to the applicable sections of the following standards:

ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves

ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Applications

ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves

ISO 10993-10 Biological evaluation of medical devices -Tests for Irritation and Skin Sensitization

ISO 10993-11 Biological evaluation of medical devices - Tests for Systemic Toxicity

ALL RESULTS OF TESTING MET ACCEPTANCE CRITERIA.

Brief Description of Clinical Tests: No new clinical tests were required to support this 510(k) notification.

CONCLUSION: The performance data support the conclusion that the subject device is as safe, as effective, and performs as well as the legally marketed device that was submitted and cleared under K081260.